

**IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF ILLINOIS  
EASTERN DIVISION**

CELSIS IN VITRO, INC.  
a Maryland Corporation,

*Plaintiff,*

v.

CELLZDIRECT, INC., a Delaware Corporation  
and wholly-owned subsidiary of INVITROGEN  
CORPORATION; and INVITROGEN  
CORPORATION, a Delaware Corporation.

*Defendants.*

Case No. \_\_\_\_\_

**DECLARATION OF JUDY MADDEN**

I, Judy Madden, declare as follows.

1. I am the Vice President of Strategic Development for Celsis International Ltd. In that capacity, I supervise and/or provide direction in the development and acquisition of technology and marketing strategies for products sold by subsidiary companies of Celsis International Ltd, among which includes Celsis In Vitro, Inc. ("Celsis IVT"). In particular, I am involved in strategic issues related to the products of Celsis IVT, including the LiverPool™ products. I have knowledge of domestic and

international sales of Celsis IVT's LiverPool™ products and the other facts stated in this Declaration, and am able to testify competently to those facts.

2. I have worked with Celsis for approximately ten years and have been employed in the life sciences field since 1983.

#### **A. BACKGROUND**

3. Celsis IVT is a subsidiary of Celsis Holdings Inc. and controls the domestic and all non-European sales of the LiverPool™ products—Celsis IVT's pooled cryopreserved hepatocyte products. Celsis In Vitro GmbH ("Celsis IVT GmbH") is a subsidiary of Celsis IVT and controls the European sales of the LiverPool™ products produced by Celsis IVT in the United States.

4. Celsis IVT has been producing and selling the LiverPool™ products in the United States since 2005. Celsis IVT also sells the LiverPool™ products to foreign countries, including for example, Japan, France, United Kingdom, and Spain. Celsis IVT GmbH sells the LiverPool™ products in Europe, though as I explained above, these products are made by Celsis IVT in the United States.

5. In July of 2006, Celsis Holdings Inc. acquired In Vitro Technologies, Inc. ("IVT") based, in part, on the valuation of the technical capabilities and intellectual property portfolio of IVT at that time. That valuation included IVT's proprietary market position and favorable growth potential created by the technology behind the Liverpool™ products.

6. Celsis IVT considers the LiverPool™ products to be its flagship products, which it uses to parlay the sales of its other products. The LiverPool™ products are available as 5-, 10-, 20-, and 50-donor mixed gender pools, as well as 10-donor male only

and 10-donor female only pools. Celsis IVT also offers the LiverPool™ products as custom blended pools based on customer specific requirements. If a customer is interested in a particular LiverPool™ product with specific characteristics, Celsis IVT will combine any number of donors to generate a custom-made LiverPool™ lot that meets that customer's specific request.

7. The Liverpool™ products are protected by one or more patents or patent applications, including U.S. Patent No. 7,604,929 ("the '929 patent"). The '929 patent was granted on October 20, 2009. REDACTED

REDACTED

8.

REDACTED

9. The sale of hepatocytes and subcellular fractions typically represent greater than REDACTED the revenues of Celsis IVT. As a subset of hepatocytes, the Liverpool™ products have represented a growing percentage of Celsis IVT's revenues, reaching as much as approximately REDACTED recent reporting periods. In fact, despite the presence copy cat products in the market, revenues of Liverpool™ products

REDACTED

REDACTED

10. The combined revenues of Celsis IVT and Celsis IVT GmbH account for REDACTED of the revenues of Celsis. Celsis publicly reported revenues of approximately \$52 million for the reporting period ending March 31, 2009.<sup>1</sup> Consequently, the financial success of Celsis IVT and Celsis IVT GmbH are critically important to the business objectives and financial viability of Celsis.

#### **B. DOMESTIC AND FOREIGN SALES**

11. By example, I have provided the sales information for the LiverPool™ products for Celsis IVT at Exhibits A. Exhibit A does not include sales information for the LiverPool™ products sold by Celsis IVT GmbH.

#### **C. XENOTECH LITIGATION**

12. In November 2009, Celsis IVT began discussions with XenoTech, LLC (“XenoTech”) regarding the ‘929 patent and XenoTech’s cryopreserved pooled hepatocyte products called CryoXTreme. Once the discussions stalled in February 2010, Celsis IVT initiated a patent infringement action against XenoTech in the United States District Court for the Northern District of Illinois. By May 2010, the parties had settled the lawsuit, XenoTech had removed the CryoXTreme products from the market, and the case was dismissed.

---

<sup>1</sup> The Celsis IVT fiscal year extends from April 1<sup>st</sup> through the following March 31<sup>st</sup>.

**D. LOST SALES TO CELLZDIRECT**

13. I understand that CellzDirect, Inc. ("CellzDirect") was selling competing cryopreserved pooled hepatocyte products by at least June 2007. In March 2008, Celsis IVT advised CellzDirect of its published patent application that disclosed the technology behind the LiverPool™ products.

14. Since Celsis IVT's notice to CellzDirect, I am aware of a number of lost sales of the LiverPool™ products, where a customer purchased the competing cryopreserved pooled hepatocyte products of CellzDirect over the LiverPool™ products, based on a lower selling price. I provided known examples below. I note however that there have been other lost sales due to CellzDirect's competing cryopreserved pooled hepatocyte products. This knowledge is based in part upon CellzDirect's periodic inventory of its competing products, though I am not entirely certain of these details and have not included any such examples in my Declaration.

15.

REDACTED

16.

REDACTED



REDACTED

17.

REDACTED

18. Despite the above-mentioned known examples, where Celsis IVT lost sales to CellzDirect, I cannot know for certain what other lost opportunities Celsis IVT has missed out on with these customers for the Liverpool™ products or other related products as a result of losing these sales. REDACTED

REDACTED

Likewise, I cannot know what other lost sales and opportunities Celsis IVT has missed out on for other customers, because I do not have comprehensive knowledge of what other sales Celsis IVT has lost due to CellzDirect's products.

19.

REDACTED

REDACTED

20.

REDACTED

Though Celsis IVT lost this sale to CellzDirect, several months later this customer resumed purchasing the LiverPool™ products. According to this customer, it was not satisfied with the CellzDirect products and considered the LiverPool™ products to be higher quality and more reliable. In other words, CellzDirect's products were of lesser quality to the LiverPool™ products. However, the customer was willing to continue buying the CellzDirect products, unless the price of the Liverpool™ product was reduced because the LiverPool™ products were apparently priced higher than the CellzDirect products. So to earn back this customer, Celsis IVT was pressured to sharply discount the price of the LiverPool™ products to achieve the sale.

21.

REDACTED

REDACTED

22.

REDACTED

23.

Without question these instances of where Celsis IVT was forced to heavily discount the Liverpool™ products has damaged Celsis IVT in the short term. Going forward over the coming years, I cannot predict for certain how much lower Celsis IVT will need to continue eroding its prices in order to achieve any future sales of the LiverPool™ products for the customers mentioned above and for the rest of its customers. Celsis IVT also cannot predict other future lost opportunities to sell its other hepatocyte and hepatocyte-derived products—sales that could be achieved as a result of the reputation and quality of the flagship LiverPool™ products.

#### **E. PRICING AND DISCOUNT STRATEGIES**

24.

REDACTED



REDACTED

25.

REDACTED

26.

REDACTED

REDACTED

27.

REDACTED

28.

REDACTED

29.

REDACTED

## F. CONFERENCES AND WORKSHOPS

30. The cryopreserved hepatocyte market, which includes the sales of pooled and single-donor cryopreserved hepatocytes, is comprised of only a small number of companies whose reputations are built, in part, by the quality of their products, services, and innovative contributions in the field of drug development.

31. Important venues to establish and build the company's reputation are the many regional, national, and international conferences that occur throughout the year. At these conferences researchers and industry experts exchange ideas, present their research, and tout their products and services to current and potential customers. A company's ability to effectively present its innovative products and their use in research—particularly those which positively contribute to quality research—enhances the reputation of that company. For Celsis IVT these conferences are critical venues for building its reputation with its customer base.

32. There are several upcoming regional, national, and international conferences where both Celsis IVT and CellzDirect will be presenting and marketing their respective pooled cryopreserved hepatocyte products. Celsis IVT will essentially be marketing its LiverPool™ products against copycat, cheaper pooled cryopreserved hepatocyte products sold by CellzDirect. These circumstances will continue to affect the sales and leadership position of Celsis IVT. Specifically, the following non-inclusive list exemplifies upcoming regional and national conferences:

Meeting Name	Date	Location
CACO	August 2, 2010	San Francisco, CA
HRA Meeting	September 4, 2010	Istanbul, Turkey

9 <sup>th</sup> Annual International ISSX	September 4-7, 2010	Istanbul, Turkey
Land O'Lakes Conference	September 13-17, 2010	Merrimac, WI
Celsis IVT Hepatocyte Users Workshop	October 6, 2010	Baltimore, MD
25th JSSX Annual Meeting	October 7-9, 2010	Saitama, Japan
NJDMDG	October 13, 2010	Somerset, NJ
CSSX Workshop	October 22-26, 2010	Shanghai, China
AAPS	November 14-18, 2010	New Orleans, LA

33. Companies often sponsor conferences for which one of their researchers may present research related to their products. For example, APSciences' Dr. Albert Li<sup>2</sup>—who acts as CellzDirect's exclusive manufacturer of its pooled cryopreserved hepatocyte products—has presented several times on the topic of cryopreserved pooled hepatocyte products at events that were co-sponsored in part by Celsis IVT and CellzDirect's parent company, Invitrogen. Dr. Li's presentations have included the same data that was generated using the cryopreserved pooled hepatocyte products which are the subject of Celsis IVT's complaint.

34. In addition to conferences, companies within this industry, including Celsis IVT and CellzDirect, conduct workshops for their customers and potential customers. Customers, particularly researchers, can participate in educational discussions with the respective company and work hands-on with that company's products. These workshops are valuable opportunities for companies to extend their scientific credibility through the use of their products in an informal, one-on-one setting. These workshops

---

<sup>2</sup> Dr. Li is also the former Chief Scientific Officer for IVT.

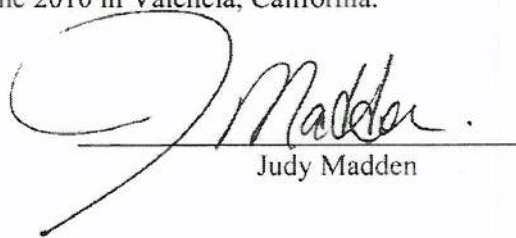
are critical avenues for establishing and solidifying the company-customer relationship and future revenue streams. For competitive reasons, companies do not invite their competitors to participate in these workshop; therefore, Celsis IVT cannot know what CellzDirect discloses to its customers about its own pooled cryopreserved hepatocyte products or its competitor's products. For example, Celsis IVT has no way of knowing whether CellzDirect is misrepresenting the LiverPool™ products to its customers which could have a negative impact to Celsis IVT's reputation and goodwill. Such damage to its reputation would likely lead to additional lost opportunities to sell its LiverPool™ products and its other products.

#### **G. INTERNAL DISRUPTION TO CELSIS IVT**

35. The continued sales of CellzDirect's cryopreserved hepatocyte products have significantly disrupted Celsis IVT's internal personnel. As a small company, Celsis IVT has only participated in one patent litigation prior to this case (explained above) and does not have permanent internal personnel who coordinate and manage litigation with outside counsel. As a result, Celsis IVT has had to disrupt the daily responsibilities of employees throughout the entire company, including those in accounting, sales, marketing, product development, strategic planning, and manufacturing—time which obviously could have otherwise been spent performing their daily responsibilities of contributing to the revenue-generating objectives of Celsis IVT. These employees, including myself, have devoted significant hours analyzing CellzDirect's products and planning for ways to address them. This lost time and the significant expenses associated with these activities cannot be recouped and will only continue so long as CellzDirect's products remain on the market.



Executed on this 21<sup>st</sup> day of June 2010 in Valencia, California.



Judy Madden